K040107

510(k) Summary of Safety and Effectiveness

JUL 27 2004

510(k) Submitter: Streck Laboratories
7002 South 109th Street
La Vista, NE 68128

Official Correspondent: Carol Thompson, Quality Assurance Manager
(402) 537-5313

Date Prepared: January 19, 2004

Names of Device:

Trade Name:	**Cyto-Chex® BCT**
Common Name:	Blood specimen collection device
Classification Name:	Blood specimen collection device, 21CFR862.1675

Predicate Device: Immunicon CellSave™, K030596

Description:

Cyto-Chex BCT consists of a standard 13 x 75mm glass blood collection tube containing 57ul of sterile K_3EDTA anti-coagulant and WBC preservative. It is manufactured with a vacuum to draw 5ml of blood by venipuncture.

Intended Use:

Cyto-Chex BCT is intended for the collection and storage of blood specimens for immunophenotyping of WBC by flow-cytometry. Recovery of lymphocyte subset cell markers of the HIV panel can be accomplished over a 7-day period following collection.

Comparison with Predicate Device:

CellSave tube is for collection and storage of specimens intended to be used for monitoring circulating epithelial (tumor) cells. It is also claimed to be applicable for monitoring T lymphocyte subsets in HIV positive patient management. The components of CellSave and Cyto-Chex BCT are similar.

Testing Performed:

Flow cytometric data for lymphocyte subset cell-surface markers was obtained by analysis of peripheral blood samples collected from multiple healthy donors. A separate clinical study was set up in which samples from HIV positive patients were collected and analyzed. Samples were collected in both K_3EDTA blood collection tubes and Cyto-Chex BCT tubes. Testing was performed over a period of 7 days using both Becton-Dickinson FACSCalibur and Beckman Coulter EPICS XL flow cytometers. Results were compared to those from fresh samples (6 hours after draw in K_3EDTA). Testing was also performed to establish stability of Cyto-Chex BCT reagent and to verify that under filling the tube would not compromise results.

Conclusions Drawn from the Tests:

The Cyto-Chex BCT tube contains a stable composition allowing the un-used tubes to be stored for at least one year at room temperature.

Bland Altman Plots, Light Scatter Dot Plots, and Correlation Coefficient results demonstrate that Cyto-Chex BCT tubes can be effectively used to collect and store clinical specimens for flow-cytometry analysis of Lymphocyte subsets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 27 2004

Ms. Kerrie Oetter
Quality Assurance Coordinator
Streck Laboratories, Inc.
7002 South 109th St.
LA Vista, NE 68128

Re: k040107
Trade/Device Name: Cyto- Chex ® BCT
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: June 24, 2004
Received: June 29 2004

Dear Ms. Oetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040107

Device Name: Cyto-Chex® BCT

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040107

Prescription Use X (Per 21 CFR 801.109) OR **Over-The-Counter Use**

(Optional Format 1-2-96)